REMARKS/ARGUMENT

Description of Amendments

No claims are currently amended. Claims 1, 2, 4-7 and 25-37 remain pending after entry of this Amendment. Reconsideration and withdrawal of the rejections are respectfully requested in view of the remarks presented below.

Rejection under 35 U.S.C. §103

I. Rejections over Jendersee in view of Helfrich and Scanlon

Claims 1, 2, 4-7, 25, 26 and 33-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,836,965 ("Jendersee") in view of U.S. Patent 5,308,338 ("Helfrich") and U.S. Patent 2,845,346 ("Scanlon").

Claims 1, 2, 4-7, 25, and 26

The Office referred to the reasons for rejection stated in the previous Office Action. With respect to claim 1, the Office stated that Jendersee is "silent concerning the retaining member(s) having a porosity to the extent of a closed pore system" but that Helfrich teaches "catheters having cuffs made from porous material" and Scanlon teaches "that sintered metal while porous, can be made to have a closed pore system."

The Office proposed to modify the Jendersee device such that the stent retainers 50, 52, 54 (Jendersee FIGS. 1, 3 and 7) are made of the porous material of Helfrich's cuffs 7, 11, 26 (Helfrich FIGS. 1 and 2). Applicant respectfully traverses.

FIRST

Jendersee teaches away from Office's proposed modification. In particular, Jendersee teaches away from elements that would hinder back-and-forth movement of the Jendersee device through body tissue. The Jendersee device is used to deliver a stent through "narrowed and tortuous vasculature," which means that the device should have "a smooth surface for easier passage through vessels" (Jendersee col. 3:3-7 and col. 7:36-39). Contrary to Jendersee's teaching, the Office's proposed modification of using the Helfrich's cuff material in the

Jendersee device would add elements that hinder passage of the Jendersee device through vessels. Helfrich's cuffs are adapted to engage body tissue to prevent movement of a catheter on which it is attached. Helfrich states that the "catheter 1 is held in position within the abdominal wall of the body by means of an outer cuff 7 and an inner cuff 8... and each engaging the abdominal wall..." (Helfrich col. 4:15-19). Helfrich's cuffs, and by extension Helfrich's cuff material, prevent "back-and-forth movements ... of the catheter with respect to ... body tissues" (see Helfrich col. 1:40-46), which would hinder an important function of the Jendersee device if added to the Jendersee device.

SECOND

The addition of Helfrich's cuff material to the Jendersee device would not have yielded predictable results to one of ordinary skill in the art. Given Jendersee's emphasis on having smooth surfaces for easy passage through vessels and the fact that Helfrich's cuff material is adapted to prevent back-and-forth movement, it would not have been reasonably predictable to one of ordinary skill in the art that using Helfrich's cuff material would still allow the Jendersee device to pass easily through narrowed and tortuous vasculature.

THIRD

The Office stated that Applicant's arguments filed March 28, 2008 were not persuasive since the "texture of the cuff or the first and second members, is not claimed and therefore, the texture of the cuff being smooth, jagged, rough, etc. is not required to be taught by the prior art" (Office Action, page 5). However, Applicant did not argue that the claimed invention requires a particular texture or that Jendersee's retainers or Helfrich's cuffs need to be smooth, jagged, or rough in order to meet elements of the claimed invention. Applicant argued that replacement of Jendersee's smooth retainers with Helfriche's rough cuffs, as proposed by the Office, was improper. Such replacement is improper for the reasons given in the Amendment filed March 28, 2008 and the reasons given above.

FOURTH

The Office cited col. 7:34-54 for its assertion that "Jendersee establishes that conventional retainers [can] be made from any implantable material" (page 6). The phrase "any implantable material" (col. 7:50-51) is akin to a description of a genus and does not by itself

render obvious any particular species associated with the pores recited in claim 1. See MPEP 2144.08, "Obviousness of Species When Prior Art Teaches Genus." In addition, even though Jendersee states that retainers "may be made from any implantable material" (col. 7:50-51), Jendersee's emphasis of allowing the device to track easily through narrowed and tortuous vessels cannot be ignored. MPEP 2141.02 VI mandates that a "prior art reference must be considered in its entirety." As indicated above, use of Helfrich's tissue engaging cuff material is contrary Jendersee's teaching. Accordingly, Jendersee's phrase "any implantable material" (col. 7:50-51) does not justify the use of Helfrich's tissue engaging cuff material.

The Office stated: "There is no reason for not making the cuffs from various materials because all of the materials set forth [in the cited references] are implantable or useable in the body so there is nothing to teach away from using various known and used materials to make cuffs or retainers" (Office Action, page 6). The Office is wrong to imply that there can be no teaching away as long as the material used in the Jendersee device is biocompatible. Different biocompatible materials may have differing characteristics and functions. As already explained above, Jendersee teaches away from using materials, such as Helfrich's tissue engaging cuff material, that would hinder back-and-forth movement of the Jendersee device.

FIFTH

The Office stated that "One of ordinary skill in the art would readily appreciate making the cuffs from material that enables the cuffs to retain their original function to retain the stent in place on the surface of the balloon catheter" (Office Action, pages 6 and 7). The Office also stated that "the outcome of success of the cuffs to retain the stent on the balloon catheter support surface" would not be changed "[a]bsent destruction or deformation of the stent" (Office Action, page 7). However, the retainers in the Jendersee device are not only intended to retain the stent. They are also intended to allow for easy passage of the stent through narrowed and tortuous vessels. Replacing the material of the Jendersee retainers with a material that engages body tissue would not allow the Jendersee retainers to retain all their original functions.

* * *

Scanlon fails to cure these deficiencies of Jendersee and Helfrich. Accordingly, Applicant respectfully submits that claim 1 is patentably allowable over Jendersee in view of

Helfrich and Scanlon. Claims 2, 4-7, 25 and 26 depend from claim 1 and are patentably allowable for at least the same reasons given for claim 1.

Claim 33

Claim 33 was regarded by the Office as providing no patentable weight contrary to MPEP 2113. MPEP 2113 states that "The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product."

Claim 33 states that the "stent support surface of the first member has been subjected to surface treatment to increase capillary permeation of the coating substance..." Capillary permeation refers to a particular surface characteristic related to surface energetics, as explained in the specification (Pub. No. 2004/0060508, para. 34). The increase in capillary permeation recited in claim 33 is not taught in Jendersee and Helfrich, individually and if combined. Nor do they teach subjecting a surface to another process in order to increase capillary permeation. Under MPEP 2113, this surface characteristic in claim 33 cannot be simply be disregarded as the Office has done.

Claim 34

In rejecting claim 34, the Office merely addressed the claimed element "the first member has a conical shape" and did not address the element "a portion of the stent support surface of the first member enters the lumen of the stent." The Office cited Jendersee col. 7, lines 44 and 45 in rejecting claim 34, but this portion of Jendersee only discloses the cuffs 50, 52 as being tapered on the side facing away from the stent 10. As shown in Jendersee FIG. 3, the tapered sides of the cuffs 50, 52 do not enter the lumen of the stent 10.

Claim 35

The cited references, individually and when combined, fail to meet the element "the third member extends through the lumen of the stent without contacting the stent." In the Jendersee device, a balloon (adjacent to ref. no. 34 in FIGS. 1-3) extends through the lumen of the stent 10 and makes contact with the stent. The Office proposed to modify the Jendersee device by either

mounting the stent 10 so as to be out of contact with the balloon either by mounting the stent at a distance above the balloon or by reducing the size of the balloon. The Office's proposed modification is improper for several reasons.

FIRST

Jendersee teaches that the balloon extending through the lumen of the stent is to be "in intimate contact with and/or surrounding [the] stent to assure stent attachment to the balloon" (Jendersee col. 3:21-24). This intimate contact, referred to repeatedly as "encapsulation" throughout Jendersee, is "effective along substantially the entire length of the stent" (col. 3:27-29). Also, Jendersee teaches that a limited amount of securement between the delivery device and the stent is undesirable because "it is not always adequate to insure that the stent will properly stay in place while advancing the stent to and through the target lesion" (col. 2:58-62). Thus, Jendersee teaches away from decreasing the amount of contact between the stent and the balloon carrying the stent. The Office's proposed modification does exactly what Jendersee teaches away from.

SECOND

The Office's proposed modification of reducing stent-balloon contact would appear to render the Jendersee device unsatisfactory of its intended purpose since doing so would increase the chance that the stent would slide off the balloon while advancing the stent through narrowed and tortuous vessels.

THIRD

Reducing stent-balloon contact as the Office proposed would not have yielded predictable results to one of ordinary skill in the art. Given Jendersee's teaching of maximizing stent-balloon contact, it would not have been predictable to one of ordinary skill in the art that the Office's proposed modification would still allow for adequate securement of the stent to prevent slippage of the stent from the balloon while advancing the stent through narrowed and tortuous vessels.

FOURTH

Jendersee teaches away from implementing a "method that increases the crossing [sic: cross sectional] profile of the delivery device thereby decreasing the device's ability to track through narrowed and tortuous vasculature" (Jendersee col. 3:2-7 and 3:11-16). Placing a stent above and out of contact with the balloon so as to rest above retainers 50, 52 at the ends of the stent 10, as the Office proposed, would increase the cross-sectional profile of the Jendersee device contrary to Jendersee's teaching. Furthermore, shrinking the balloon to a smaller diameter without also crimping the stent into contact with the smaller diameter balloon, as the Office proposed, would keep the overall cross sectional profile of the assembly larger than necessary contrary to Jendersee's teaching.

FIFTH

Increasing the cross-sectional profile of the Jendersee device would make it more difficult to track through narrowed and tortuous vessels, thereby rendering the Jendersee device unsatisfactory of its intended purpose contrary to MPEP 2143.01 IV ("the proposed modification cannot render the prior art unsatisfactory for its intended purpose").

Claim 36

In rejecting claim 36, the Office asserted that Jendersee's disclosure of tapers meets the "narrowed portion" recited claim 36. However, the tapers on Jendersee's cuffs are located at distances away from the stent and on the sides of the cuffs facing away from the stent 10 as shown in Jendersee FIG. 3. Therefore, the portion of the Jendersee device between cuffs 50, 52 fails to meet "the third member extends from the narrowed portion of the stent support surface of the first member to the narrowed portion of the stent support surface of the second member," as recited in claim 36.

II. Rejections over Jendersee in view of Helfrich

Claims 27-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jendersee in view of Helfrich for reasons set forth in the previous Office Action.

FIRST

The Office's rejection is improper for the reasons given above with respect to claim 1. That is, Jendersee teaches away from the Office's proposed modification of the Jendersee device to include Helfrich's tissue-engaging cuff material. Also, the Office's proposed modification would not have yielded predictable results to one of ordinary skill in the art of allowing the Jendersee device to pass easily through narrowed and tortuous vessels.

SECOND

In addition, Jendersee and Helfrich fail to teach "the first and second elements capable of being moved relative to each other to secure and release the stent," as recited in independent claims 27, 31, and 32. The Jendersee device comes with the stent 10 attached to the retainers 50, 52. So moving the retainers 50, 52 relative to each would likely deform the stent 10.

Claims 28-30 depend from claim 27 and are patentably allowable for at least the same reasons given for claim 27.

III. Rejections over Jendersee in view of Helfrich, Scanlon, and Corvi

Claim 37 was rejected under 35 U.S.C. §103(a) as being unpatentable over Jendersee in view of Helfrich and Scanlon as applied to claim 1, and further in view of U.S. Patent 5,879,499 ("Corvi").

Claim 37 recites that "the first member is connected to a motor capable of rotating the first member or of translating the first member." As to Jendersee, Helfrich, and Scanlon, the Office stated that "none teach or suggest the first member (i.e., collar or cuff or retainer) being connected to a motor to rotate the first member," but the Office proposed to modify the Jendersee-Helfrich-Scanlon combination to include a motor in order to "translate or rotate the collar or cuff relate [sic: relative] to the surface of the balloon catheter as evidenced by Corvi (col. 12, lines 59-63 and col. 19, lines 1-19)."

FIRST

Contrary to the Office's assertion, Corvi does not teach "a motor capable of rotating or translating," as recited in claim 37.

Col. 12:59-63 cited by the Office is the only place in Corvi that expressly recites a "motor." This passage does not describe a motor capable of rotating or translating; it merely describes a motor for inflating and deflating an occlusion balloon 110 (Corvi FIG. 5A). Col. 12:59-63 states that inflation and deflation of the occlusion balloon 110 is performed "using an ordinary syringe" or "using an inflation device which provides a mechanical advantage or that is powered by compressed air or an electric motor." Applicant submits that the motor in this passage is merely a motorized pump capable of delivering air to the balloon and not is not capable of rotating or translating a collar at one end of the balloon.

Col. 19:1-19 cited by the Office does not teach or suggest the use of a motor. This passage relates to FIG. 9A, which does not show a motor. This passage merely describes rotating or proximally moving a collar 540 (FIG. 9A) on which a balloon is attached. Importantly, movement of the collar is performed only before or after the balloon has been deflated or inflated, which means that rotation or movement of the collar does not itself inflate or deflate the balloon. As such, there is no teaching or suggestion that the motor in col. 12:59-63, which is used to inflate and deflate the balloon, is used in Corvi col. 19:1-19 to rotate or move the collar 540 on which the balloon is attached.

SECOND

The Office reasoned that adding a motor to the Jendersee device would "provide for hands-free placement of the at least one collar/cuff/retaining member on the surface of catheter as well as for an alternative means facilitating inflating/deflation of the balloon catheter." None of these reasons for modifying the Jendersee device are valid.

First, there is no need for hands-free placement or movement of the Jendersee retainers 50, 52 relative to other parts of the Jendersee device. This is because the Jendersee device comes with the stent 10 attached to the retainers 50, 52.

Second, a person of ordinary skill in the art would not rotate one of the retainers 50, 52 in Jendersee as an alternative means facilitating inflating/deflation of the balloon catheter because

doing so would likely deform the stent or dislodge the stent out of position. Jendersee's retainers 50, 52 are used to retain the stent 10. Thus, rotation of one of the Jendersee retainers 50, 52 prior to inflation of the balloon, as is done with the collar 540 in Corvi (FIG. 9A), would twist and likely deform the Jendersee stent 10. When inflated, the Jendersee balloon pushes the stent 10 against the vessel wall at a carefully selected position within the vessel. The Jendersee balloon is then deflated to allow it to be pulled away from the stent while the stent remains at the carefully selection position (see Jendersee claim 14). Rotation of one of Jendersee's retainers 50, 52 after inflation or during deflation would twist the Jendersee balloon just as the Corvi balloon 510 is twisted (see Corvi FIGS. 9A and 9B), which would in turn deform the Jendersee stent 10 or move it out of position. Accordingly, a person of ordinary skill in the art would not have modified the Jendersee device with a means of rotating Jendersee's balloon to facilitate inflation or deflation.

Conclusion

In light of the foregoing amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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